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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,919	08/26/2003	Paul Joseph Dominowski	PC25246	2440

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EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
08/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSKala@Pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/647,919	DOMINOWSKI, PAUL JOSEPH	
	Examiner	Art Unit	
	SHARON HURT	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-23,25 and 28-75* is/are pending in the application.

4a) Of the above claim(s) *12-19 and 32-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-23, 25 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *12-23,25 and 28-7* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 16, 2009 has been entered.

2. The amendments to the claims filed July 16, 2009 have been acknowledged and entered. Claim 20 is currently amendedF.

3. Claims 12-23, 25, 28-75 are pending. Claims 12-19 and 32-75 have been withdrawn from consideration. Claims 20-23, 25 and 28-31 are under examination. Applicant's state in the preliminary remarks on page 8 and on page 10 of the remarks filed July 16, 2009 that claim 21 has been canceled. Claim 21 is marked "previously presented" in the amendments to the claims submitted July 16, 2009.

Claim Rejections - Withdrawn

4. The rejection of claims **20-23, 25 and 28-31** under 35 U.S.C. 103(a) as being unpatentable over Bowland et al. and Fulton et al. (Vaccine, 15 September 2000, Vol. 19, No. 2-3, pages 264-274) in view of Brake et al. (US Patent No. 6,787,146, Sep. 2004, Publication 16 May 2002, US2002/0058046) **is withdrawn** pursuant Applicants amendment to claim 20.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-23, 25 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowland et al. and Fulton et al. in view of Lidgate et al. (Pharmaceutical Research, 1989, Vol. 6, No. 9, pages 748-752) and Brake et al.

Bowland discloses current commercial vaccines available in Canada for bovine respiratory disease. Vaccines include infectious bovine rhinotrachetitis virus [(IBRV), bovine herpesvirus-1, (BHV-1)], bovine viral diarrhea virus (BVDV), bovine respiratory syncytial virus (BRSV), parainfluenza-3 virus (PI-3), and bacterial antigens including *Leptospira* serovars (page 33 and Table 1 pages 43-45) (*as relates to claim 20*). Some of the multi-vaccines included adjuvants (Table 1, pages 43-45) (*as relates to claims 22, 23 and 25*). Bowland teaches the vaccine compositions and intended use of the multi-vaccines. However Bowland does not teach that the vaccine is microfluidized, a vaccine composition comprising BVDV types 1 and 2 in the same vaccine, a vaccine composition with an adjuvant comprising Quil A, lecithin and oil blend and cholesterol, or indicate if the BVDV strains are cytopathic or noncytopathic.

Fulton teaches a vaccine composition comprising BVDV types 1 and 2 (see Table 1, Vaccine 3). Fulton also teaches BVDV has two biotypes, cytopathic (CP) and noncytopathic (NCP) (page 264, 1st column) (*as relates to claims 28-31*). Fulton further teaches vaccine containing modified live virus (MLV) (inactivated *as relates to claim 21*) (page 264, 2nd

column). However Fulton does not teach the vaccine is microfluidized or a vaccine composition with an adjuvant comprising Quil A, lecithin and oil blend and cholesterol.

Lidgate teaches a microfluidization process for vaccine compositions which produces the most stable and elegant emulsion and also elicited equivalent response in the animal model tested (Abstract) (*as relates to claim 20*). Lidgate teaches microfluidized emulsions benefit from decreased particle size, increased stability, and greater mixing efficiency, which attributes lend themselves to commercial viability for parenteral emulsions (page 752, 1st column, 1st paragraph). Lidgate also teaches the use of adjuvants in vaccine compositions (page 748, 1st column) (*as relates to claims 22 and 23*). However Lidgate does not teach a vaccine composition with an adjuvant comprising Quil A, lecithin and oil blend and cholesterol.

Brake discloses a vaccine for cattle against bovine Neospora comprising a veterinary acceptable adjuvant comprising SEAM62 (column 8, lines 36-50) which comprises an oil-in-water emulsion containing Quil A, lecithin and cholesterol (column 12, lines 59-67) (*as relates to claims 22, 23 and 25*). However Brake does not teach vaccine for cattle comprising BHV-1, PIV3, BRSV, BVDV-1 and BVDV-2.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use a microfluidized composition in the vaccine taught by Bowland and Fulton because Lidgate teaches benefits of a microfluidized emulsion with a reasonable expectation of success.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to include both BVDV types I and II in the vaccine composition to

protect the cattle against both pathogens because Fulton teaches a cattle vaccine comprising both type I and II with a reasonable expectation of success based.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use a adjuvant that is suitable for cattle in the vaccine composition taught by Bowland and Fulton because Brake teaches the adjuvant mixture is safe and effective in cattle with a reasonable expectation of success.

Response to Arguments

6. Applicant's arguments have been fully considered but they are not persuasive in light of the new obviousness rejection set forth *supra*. Applicants argue "Bowland do not teach microfluidized compositions." The new reference Lidgate teaches the advantages of a microfluidized composition. Applicants argue "Fulton… makes no mention of an adjuvant or of microfluidized compositions". The adjuvants are taught by Brake and the microfluidization is taught by Lidgate. The combination of references teaches the instant invention. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue "while Brake demonstrate that the adjuvant works for a homongenate parasitic vaccine, they do not demonstrate that the adjuvant works in a whole cell viral vaccine." Bowland teaches the multi-vaccines comprise adjuvants and Lidgate teaches the use of adjuvants in vaccine preparations. Brake teaches about adjuvants used in animal vaccines especially

commonly used in cattle vaccines. While Brake may not use the same pathogens in a vaccine, Brake teaches the combination of Quil A (a saponin), lecithin in an oil-in-water emulsion and cholesterol can be used in the same vaccine composition and are safe in cattle. Applicants argue "combining the secondary references of Fulton and Brake with Bowland does not make up for the deficiencies in Bowland. Even when combined the references do not yield Applicants' invention." In contrast to Applicants assertions, the combination of references teaches the limitations of the instant invention.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M, T, Th, F 8:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Hurt/
Examiner, Art Unit 1648
July 29, 2009

/Robert C. Hayes/
Primary Examiner, Art Unit 1649